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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/628,554

07/29/2003

David Comings

1954-390

3705

6449

7590

05/23/2007

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WASHINGTON, DC 20005

EXAMINER

KAPUSHOC, STEPHEN THOMAS

ART UNIT

PAPER NUMBER

1634

NOTIFICATION DATE

DELIVERY MODE

05/23/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/628,554

Applicant(s)

COMINGS ET AL.

Examiner

Stephen Kapushoc

Art Unit

1634

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 April 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 11 April 2007. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1, 4, 7, 8.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because: Applicants Remarks f 04/16/2207 have been fully and carefully considered. Applicant has traversed the rejection of claim 8 under 35 USC 112 1st as new matter. Applicants assert that from the presentation of data in the specification at pages 7-10, one of ordinary skill in the art would recognize that a subject homozygous for the CCR5 delta 32 mutation would be expected to have a shorter survival time than a heterozygous subject. The examiner maintains that while the specification presents comparisons between heterozygous and homozygous-normal individuals, as well as data regarding combined homozygous-deletion and heterozygous individuals as a population, there is not teaching or contemplation of an additive effect of the mutation in a homozygous-deletion versus a heterozygous individual.

With similar regard to Claim 8 for the lack of enablement rejection, there is not evidence of the causality or mechanism for ant effect of the delta 32 deletion mutation with survival time with MS. As such there the specification does not indicate that there is any reliably determined and significant difference in the survival of a heterozygous versus a homozygous-deletion individual. The specification does not tech if the mutation is for example, a dominant negative mutation, where the inclusion of an additional mutant allele in the homozygous individual will not further effect the phenotype seen in the heterozygous individual. Applicants traversal of the rejection of claims under 35 USC 112 1st¶ for lack of enablement has been addressed in the Office Action of 10/11/2006. Applicant has not provided any evidence in the instant specification which, in view of the unpredictability of the method as demonstrated by the cited prior art, provides for a method that is reliable for the prediction of survival time with MS.

Applicants traversal of the rejection of claims under 35 USC 103 as obvious has been addressed in the Office Action of 10/11/2006. Applicant has not provided a convincing argument or any evidence as to why the cited references of Barcellos et al and Midgard et al do not render obvious a method in which CCR5 mutation is predictive of survival rate with MS.


BJ FORMAN, PH.D.
PRIMARY EXAMINER